Applicants: Shulman et al. Application No.: 10/576,239

Examiner: T. J. Mahyera

REMARKS

Status of the Claims

Claim 25 has been amended. New claims 31-36 have been added. Claims 1-12 were

cancelled in the Preliminary Amendment. Claims 13-36 are presented for the Examiner's review and

consideration. Applicants believe the claim amendments and accompanying remarks herein serve

to clarify the present invention and are independent of patentability. No new matter has been

added.

Election

In response to the restriction requirement, Applicants elect, with traverse, Group II,

including claim 25 as amended herein, drawn to a method of enhancing dietary calcium absorption,

bone formation, and bone mass maximization in children or adults.

In response to the requirement for election of a single species of edible lipid from the group

of edible lipids recited in claims 13 and 25-30 as pending herein, Applicants provisionally elect, with

traverse, a glyceride-based lipid having over 50% mono- and polyunsaturated fatty acids at positions

sn-1 and sn-3 of the glycerol backbone and a high level of palmitic acid at position sn-2 of the

glycerol backbone.

Claim 25 and new claims 31-36 read on the elected Group II and species. Since new claims

31-36 are drawn to methods for enhancing dietary calcium absorption, bone formation, and bone

mass maximization, they are encompassed within the scope of the elected Group II.

Applicants respectfully reserve the right to file one or more divisional applications

directed to non-elected subject matter in this application, and to rejoin withdrawn claims based

on allowable subject matter.

Amendments to the Claims

No new matter has been added by the amendments to claim 25 made herein. This claim

has been amended to delete the phrase "bone enhancement" as the phrases "bone formation" and

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"bone mass maximization" are bone enhancements accomplished by carrying out the claimed methods. This claim has also been amended to clarify that the method may also be used by adults. Support for this amendment can be found in the specification as originally filed. See, for example, paragraphs [0022]; [0023]; [0048]; [0050]; [0057] and Examples 10-17 at paragraphs [0078]-[0085] of the published application; U.S. Patent Application Publication 2008/0058415 A1, hereinafter "published application." Claim 25 has also been amended to clarify that the edible lipid includes a high level of palmitic acid at position sn-2 of it's glycerol backbone. Support for this amendment can be found in the specification as originally filed. See, for example, paragraphs [0006]; [0040]; and Example 1 at paragraph [0067] of the published application. Claim 25 has been amended to correct a typographical error; delete the term "chains" and replace with the term "chain." Additionally, claim 25 has been amended to clarify that the edible lipid can be included in a food article. Support for this amendment can be found in the specification as originally filed. See, for example, paragraphs [0033]; [0034]; and [0046]-[0048] of the published application.

No new matter has been added by the addition of claims 31 and 32. These claims apply subject matter of pending claims to the method of claim 25 as amended herein. Specifically, claim 31 incorporates subject matter of claim 16 and claim 32 incorporates subject matter of claim 24.

No new matter has been added by the addition of claim 33. Claim 33 clarifies that the dietary ingredient administered by carrying out the claimed method can be a calcium supplement for supplementing a subject's dietary intake of calcium. Support for this new claim can be found in the specification as originally filed. *See*, for example, paragraphs [0035]; [0049]-[0051] and [0058] of the published application.

No new matter has been added by the addition of claim 34. Claim 34 clarifies that the edible lipid administered when carrying out the claimed method can be used as a replacement for unhealthy oils and fats characterized by a relatively high degree of fatty acid saturation at the *sn*-1 and *sn*-3 positions often present in diets of young children, adolescents, and young people. Support for this new claim can be found in the specification as originally filed. *See*, for example, paragraph [0054] of the published application.

No new matter has been added by the addition of claim 35. Claim 35 clarifies a method

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for preparing a dietary ingredient for administration during implementation of the described methods. Support for this new claim can be found in the specification as originally filed. *See*, for example, paragraph [0045] of the published application.

No new matter has been added by the addition of claim 36. Claim 36 has been added in light of the provisional election of species and clarifies that, after consumption and during digestion, the elected glyceride-based lipid does not generate (or generates in very small amounts) indigestible calcium complexes, and thus, acts to enhance calcium absorption by preventing excretion of dietary calcium in the form of the indigestible complexes. Support for this new claim can be found in the specification as originally filed. *See*, for example, paragraph [0041] of the published application.

<u>Traversal of the Requirements for Election</u>

The Examiner asserts that the instant application contains groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Specifically, the Examiner considers the edible lipids (of the Markush group recited in claims 13 and 25-30) that do not inhibit mineral absorption to be the common technical feature shared by the designated groups of inventions. However, although the Examiner identifies a common technical feature shared by the groups, he concludes that the "edible lipids" do not make a contribution over the prior art.

Applicants respectfully traverse the restriction requirement with regard to method claims 25-30.

Claims 25-27 are drawn to methods for enhancing dietary calcium absorption, bone formation, and bone mass maximization. Claims 28 and 29 are drawn to methods for treatment of diseases involving insufficient calcium absorption and defective bone formation. The treatment involves carrying out the method of claim 25. Claim 30 is drawn to a method for enhancing energy by enhancing mineral absorption, which also involves carrying out the method of claim 25. Thus, although all of the recited methods do involve administration of an edible lipid that does not inhibit mineral absorption, the methods also all accomplish the same goal; *i.e.* enhancement of dietary mineral absorption, particularly calcium, in order to provide the claimed effects such enhanced energy, treatment of disease, enhanced bone formation, by administration

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of the edible lipid. Therefore, the use of the described edible lipids for enhancement of dietary mineral absorption should be considered a novel technical feature shared by all of the recited methods.

Accordingly, Applicants respectfully urge the Examiner to reconsider and withdraw the requirement for restriction, at least with regard to the method claims.

Additionally, the Examiner asserts that the instant application contains claims directed to more than one species of the generic invention. Specifically, the Examiner appears to consider each type of edible lipid of the Markush group recited in claims 13 and 25-30 to represent a separate species.

Applicants submit that this requirement for an election of species is improper, and therefore, respectfully traverse the requirement.

Applicants consider the requirement for election of species to be improper for several reasons. First, when requiring an election of species an Examiner should: (1) identify the species from which an election is to be made; (2) provide a reason why the restriction is necessary; and (3) identify the claims considered generic. *See* MPEP 809.02(a). In the instant case, the Examiner does not identify what he considers to be the generic invention or which claims he considers generic. Further, the Examiner concludes only that the edible lipids are considered not so linked as to form a single general inventive concept without providing any reason or explanation for this conclusion.

When there is no disclosure of a relationship between species, the species are properly designated as independent. *See* MPEP 808.01(a). In the instant case, the edible lipids designated by the Examiner as separate species are claimed as "lipids that do not inhibit mineral absorption and/or enhance mineral absorption and intake" and are repeatedly described as such throughout the specification as originally filed. *See*, for example, paragraph [0025] of the published application. Therefore, there is clear disclosure of a relationship between the edible lipids, and therefore, each edible lipid can not properly be considered an independent species.

When two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive. For example, species properly described as "mutually exclusive", are defined by different limitations, *i.e.* limitations which apply to one of the species do not apply to the other species and/or vice versa. *See* MPEP 806.04(f). As noted

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above, the edible lipids designated by the Examiner as separate species are both claimed and

described as "lipids that do not inhibit mineral absorption and/or enhance mineral absorption and

intake." Thus, the same limitations are placed on each edible lipid recited, and therefore, the

edible lipids can not properly be considered mutually exclusive species.

Accordingly, in light of the all of the above, Applicants respectfully urge the Examiner to

reconsider the propriety of the requirement for election of species and withdraw the requirement.

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for

an examination on the merits, and early action is respectfully requested. If there are any questions

regarding this response or the application in general, a telephone call to the undersigned would

be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a one month extension of time pursuant to Section 1.17 (a)(1) in the amount of \$65 is

believed to be due and is being paid via credit card. No other fees are believed to be due at this

time. However, please charge any other required fee (or credit any overpayments of fees) to the

Deposit Account of the undersigned, Account No. 500601 (Docket no. 7056-X08-022).

Respectfully submitted,

/Katharine F. Davis Wong/

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